

REMARKS/ARGUMENTS

This letter is responsive to the Office Action dated **July 9, 2003**. Under separate sheet of cover, applicant encloses a request for a one-month extension of time.

Claim Amendments and new claim 20

Applicant has amended Claim 1 to orient the piston within the syringe body. Specifically, element (b) now specifies that the upper surface of the piston is closer to the neck end of the syringe body than the lower surface of the piston when the piston is inserted into the open rimmed end of the syringe body. This amendment provides context for element (d), which provides that the piston is supported with its upper surface spaced from the rimmed end of the syringe body and substantially concentric therewith such that a gap exists between the upper surface of the piston and the rimmed end of the syringe body. This gap permits sterilization of the syringe body and the piston by a sterilizing gas. Applicant submits that the amendment to Claim 1 and new claim 20 do not add new subject matter.

Anticipation Under 35 USC 102(b) & (e)

In the Office Action, the Examiner rejects Claims 1-3, 5, 6, and 7 under 35 U.S.C. 102(b) as being anticipated by Wilburn (US Patent No. 2,860,635). Reconsideration thereof is requested in light of Applicant's amendments and the following arguments.

On pages 2-3 of the Office Action, the Examiner provides the following:

Wilburn discloses a syringe body (50) with a rimmed end (Figure 1). The device also includes a piston (79), a sleeve (82) and piston support means (76). The support means is integrally formed with the sleeve and includes a support surface (77) located radially inwardly of the inner surface of the syringe body side wall and forms a gap (see Figures 1, 23, and 25)...(Emphasis Added).

Claim 1 as amended is directed to an assembly having a piston support means with a support surface on which a piston is supported with its upper surface (e.g., the surface closer to the neck end of the syringe body) spaced from the rimmed end of the syringe body such that a gap exists between the upper surface of the piston and the rimmed end of the syringe body. This gap permits sterilization of the syringe body and the piston by a sterilizing gas.

In contrast, Wilburn teaches an assembly having a unique structure that permits sterilization of a barrel 50 and a piston 79 by a sterilizing gas in a different way. Wilburn teaches a barrel 50 having a cylindrical wall 62 that defines a bore 63, a circular rib 64 that serves as a piston stop, a counterbore 65 in a rear zone 66 that provides a socket that has a larger diameter than the diameter of the bore 63, and a rear edge 68. As noted by the Examiner, during the sterilization process the piston 79 resides within the counterbore 65 which provides a space between the inner wall of the rear zone 66 of the barrel 50 and the side surface of the piston plug 79 for free passage of sterilization gas therebetween (see also col. 7, lines 31-42 and Figure 1).

Importantly, Wilburn teaches an assembly having a space between the inner wall of the rear zone 66 and the side surface of the piston 79, whereas the invention as claimed in amended Claim 1 requires a gap between the upper

surface of the piston and the rimmed end of the syringe body. Nor is the structure of Wilburn an equivalent of the claimed invention. Accordingly, applicant respectfully submits that Wilburn does not anticipate amended Claim 1.

Claims 2-3, 5, 6, and 7 all depend from amended Claim 1. Accordingly, applicant submits that Claims 2-3, 5, 6, and 7 are allowable for at least the reasons given for amended Claim 1.

Nor would the subject matter of Claims 1-3, 5, 6, and 7 be obvious in view of Wilburn, it is submitted.

In the Office Action, the Examiner rejects Claims 1-2, and 7-10 under 35 U.S.C. 102(b) as being anticipated by Helixon et al. (US Patent No. 4,091,812). Reconsideration thereof is requested in light of Applicant's amendments and the following arguments.

On page 3 of the Office Action, the Examiner provides:

Helixon et al. discloses a syringe body (12) with a rimmed end (Figure 2). The device also includes a piston (18), a sleeve (32) and piston support means (34). The support means is integrally formed with the sleeve and includes a support surface (48) located radially inwardly of the inner surface of the syringe body side wall and forms a gap (38)... As shown in Figure 2, the gap (38) thickness is about the thickness of the syringe body wall which forms an annular recess... (Emphasis Added).

Helixon et al. teaches an assembly having a different structure from that claimed in the present invention. The assembly is adapted to facilitate discharge of one or more predetermined dosages from a barrel 12 while protecting the barrel 12 from fracture during operation. As noted by the Examiner, the outside diameter of an actuator shaft 34 and the inner diameter of a sleeve 36 are sized such that the wall of the barrel 12 may be readily received in an annular recess

38 to allow longitudinal movement of the operator means 32 relative to the barrel 12 toward the discharge end 14 of the barrel 12 (see also col. 3, lines 30-38 and Figure 2.) A plunger 18 is positioned within the barrel 12 at all times.

Importantly, Helixon et al. teaches an assembly having an annular recess 38 between the actuator shaft 34 and the sleeve 36, whereas the invention as claimed in amended Claim 1 requires a gap between the upper surface of the piston and the rimmed end of the syringe body. As noted above, Helixon et al. teaches an assembly wherein the plunger 18 is positioned within the barrel 12 at all times. Nor is the structure of Helixon et al. an equivalent of the claimed invention. Accordingly, applicant respectfully submits that Helixon et al. does not anticipate amended Claim 1.

Claims 2 and 7-10 all depend from amended Claim 1. Accordingly, applicant submits that Claims 2 and 7-10 are allowable for at least the reasons given for amended Claim 1.

Nor would the subject matter of 1-2 and 7-10 be obvious in view of Helixon et al., it is submitted.

In the Office Action, the Examiner rejects Claims 1-4 and 7 under 35 U.S.C. 102(b) as being anticipated by Poux (US Patent No. 2,453,590). Reconsideration thereof is requested in light of Applicant's amendments and the following arguments.

On page 4 of the Office Action, the Examiner provides:

Poux discloses a hypodermic syringe that includes a syringe body (4) with a rimmed end (Figure 6). The device also includes a piston (16), a sleeve (14), and piston support means (23). The support means is integrally formed with

the sleeve and includes a support surface (Figure 6) located inwardly of the inner surface of the syringe body side wall and forms a gap (29) (Figure 6)... (Emphasis Added).

Poux teaches an assembly having a different structure from that claimed in the present invention. The assembly facilitates discharge of a medicament from a capsule 4. As noted by the Examiner, the outside diameter of an inner cylindrical portion 23 and the inner diameter of an outer cylindrical portion 28 are sized such that the wall of the capsule 4 may be readily received in an annular recess 29 to allow longitudinal movement of the plunger member 14 relative to the capsule 4 toward the discharge end of the capsule 4 (see also col. 5, lines 49-51 and Figure 6). A stopper 16 is positioned within the capsule 4 at all times.

Importantly, Poux teaches an assembly having an annular recess 29 between the inner cylindrical portion 23 and the outer cylindrical portion 28, whereas the invention claimed in amended Claim 1 requires a gap between the upper surface of the piston and the rimmed end of the syringe body. As noted above, Poux teaches an assembly wherein the stopper 16 is positioned within the capsule 4 at all times. Nor is the structure of Poux an equivalent of the claimed invention. Accordingly, applicant respectfully submits that Poux does not anticipate amended Claim 1.

Claims 2-4 and 7 all depend from amended Claim 1. Accordingly, applicant submits that Claims 2-4 and 7 are allowable for at least the reasons given for amended Claim 1.

Moreover, it is submitted that there is no basis to conclude that the subject matter of Claims 1, 2-4 and 7 would be obvious in light of Poux.

In the Office Action, the Examiner rejects Claims 1 and 5-7 under 35 U.S.C. 102(e) as being anticipated by Peterson et al. (US Patent No. 6,156,014). Reconsideration thereof is requested in light of Applicant's amendments and the following arguments.

On page 4 of the Office Action, the Examiner provides:

Peterson discloses a dispenser that includes a syringe body (1) with a rimmed end (15). The device also includes a piston (8), a sleeve (14), and piston support means (12). The support means 12 is integrally formed with the sleeve and includes a support surface (Figure 1) located radially inwardly of the inner surface of the syringe body wall and forms a gap (Figure 1)... (Emphasis Added).

Peterson et al. teaches an assembly having a different structure from that claimed in the present invention. The assembly facilitates discharge of a dosage of a drug from a cylinder 1. The drug to be dispensed is stored in a chamber 7 in piston 8. When the plunger 4 is pressed into the cylinder 1, a penetrator 11 penetrates a membrane sealing one end of the chamber 7. When the plunger 4 is pressed home into the cylinder, a second penetrator 12 carried by the plunger 4 penetrates another membrane sealing the other end of the chamber 7. At this point, the air compressed by the plunger 4 in the cylinder 1 will escape through the outlet pipe 3 entraining the drug in the chamber 7 (see col. 2, lines 48-64 and Figure 1). The piston 8 is positioned within the cylinder 1 at all times.

Importantly, Peterson et al. teaches an assembly having a penetrator 12 carried by the plunger that penetrates a membrane sealing a chamber in the piston 8, whereas the invention as claimed in amended Claim 1 requires a piston support means. Additionally, Peterson et al. teaches an assembly having the

piston 8 positioned within the cylinder at all times, whereas the invention as claimed in amended Claim 1 requires a gap between the upper surface of the piston and the rimmed end of the syringe body. Nor is the structure of Peterson an equivalent of the claimed invention. Accordingly, applicant respectfully submits that Peterson et al. does not anticipate amended Claim 1.

Claims 5-7 all depend from amended Claim 1. Accordingly, applicant submits that Claims 5-7 are allowable for at least the reasons given for amended Claim 1.

Moreover, it is submitted that there is no basis to conclude that the subject matter of Claims 1, and 5-7 would be obvious in light of Peterson et al.

New claim 20 has been added and it is respectfully submitted that none of the prior art anticipates claim 20 or renders claim it obvious.

For the reasons above, the Applicants submit that the claims are in condition for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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